IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

CURTIS L. MCELDOWNEY, JR., et al.,	CASE NO. 3:05 CV 199
Plaintiffs,	JUDGE WALTER RICE
v.	
G.D. SEARLE, L.L.C., et al.,	
Defendants.	

DEFENDANTS' ANSWER TO PLAINTIFFS' FIRST AMENDED COMPLAINT
(Jury Demand Endorsed Hereon)

Defendants G.D. Searle LLC, Pharmacia Corporation, and Pfizer Inc.,[1] for their Answer to Plaintiffs' First Amended Complaint and Jury Demand state as follows:

PARTIES

1. Defendants deny that the claims brought in this action involve common questions of law and fact pursuant to Ohio R. Civ. P. 42. Defendants deny for want of knowledge the remaining allegations contained in paragraph 1, including subparts a-iii, of Plaintiffs' Complaint.

2. Defendant G.D. Searle LLC ("Searle") admits that it is an Illinois Corporation, which is registered to do business in the State of Ohio and can be served through its statutory

[1] As noted in Defendants' Notice of Removal (filed with the Court on May 31, 2005), Defendant G.D. Searle LLC was improperly captioned in Plaintiffs' Complaint and Amended Complaint as "G.D. Searle, L.L.C." and Defendant Pfizer Inc. was improperly captioned as "Pfizer, Inc." In addition, it was noted that the defendant named as "Monsanto Company" is now known as Pharmacia Corporation.

agent CT Corporation System located at 1300 East Ninth Street in Cleveland, Ohio. Further answering, during certain periods of time it tested, co-promoted and developed Celebrex® (Celecoxib) (hereinafter "Celebrex®"). During certain periods of time, Celebrex® was manufactured for Searle. Defendant Searle denies the remaining allegations contained in paragraph 2 of Plaintiffs' First Amended Complaint.

3. Defendant Pharmacia Corporation admits the allegations contained in paragraph 3 of Plaintiffs' First Amended Complaint.

4. Defendant Pharmacia Corporation formerly known as Monsanto Company, and incorrectly named in the First Amended Complaint as "Monsanto Company," admits that it is a Delaware Corporation. Further answering, this Defendant admits that, during certain periods of time, it marketed Celebrex®. This Defendant denies the remaining allegations contained in paragraph 4 of Plaintiffs' First Amended Complaint.

5. Defendant Pfizer Inc. admits that it is a Delaware corporation that is licensed and registered to do business in the State of Ohio and that it can be served through its statutory agent CT Corporation System located at 36 East Seventh Street, Suite 2400 in Cincinnati, Ohio. Further answering, Defendant Pfizer Inc. admits that, during certain periods of time, it marketed and promoted Celebrex®. Defendant Pfizer Inc. denies the remaining allegations contained in paragraph 5 of Plaintiffs' First Amended Complaint.

6. Defendants deny for want of knowledge the allegations contained in paragraph 6 of Plaintiffs' First Amended Complaint.

7. Defendants deny for want of knowledge the allegations contained in paragraph 7 of Plaintiffs' First Amended Complaint.

8. Defendants admit that they are foreign corporations and have done business in Ohio. Defendants deny for want of knowledge the remaining allegations contained in paragraph 8 of Plaintiffs' First Amended Complaint.

9. Defendants deny for want of knowledge the allegations contained in paragraph 9 of Plaintiffs' First Amended Complaint.

BACKGROUND

10. The allegations contained in the first sentence of paragraph 10 of Plaintiffs' First Amended Complaint are denied as phrased. Defendants admit that Celebrex® is a prescription medication drug which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; and (5) to reduce the number of colorectal polyps in patients with familial adenomatous polyposis, as an adjunct to usual care (e.g. endoscopic surveillance, surgery). Defendants also state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants deny the remaining allegations contained in paragraph 10 of Plaintiffs' First Amended Complaint.

11. Defendants state that Celebrex® was marketed, advertised, and sold consistent with applicable law and its FDA approved package insert. Defendants deny the remaining allegations contained in paragraph 11 of Plaintiffs' First Amended Complaint.

12. Defendants deny the allegations contained in paragraph 12 of Plaintiffs' First Amended Complaint.

13. Paragraph 13 of Plaintiffs' First Amended Complaint states Plaintiffs' own assertions and legal conclusions to which no response is required. To the extent a response is

required, Defendants deny the allegations contained in paragraph 13 of Plaintiffs' First Amended Complaint.

14. Defendants deny the allegations contained in paragraph 14 of Plaintiffs' First Amended Complaint.

15. Defendants refer to and incorporate their responses in this Answer to paragraphs 2, 4 and 5 of Plaintiffs' First Amended Complaint as though fully rewritten herein. Defendants deny the remaining allegations contained in paragraph 15 of Plaintiffs' First Amended Complaint.

16. Defendants deny the allegations contained in paragraph 16 of Plaintiffs' First Amended Complaint.

17. Defendants deny that Plaintiffs brought their action in the "United States District Court for the Montgomery District of Ohio, Civil Division (sic)." Further answering, Defendants admit that the amount sought in Plaintiffs' First Amended Complaint exceeds the jurisdictional limits of the lower courts that would otherwise have jurisdiction over this matter.

FIRST CAUSE OF ACTION

NEGLIGENCE

18. Defendants incorporate each and every admission and denial set forth in paragraphs 1 through 17 above as though fully rewritten herein.

19. Defendants deny the allegations contained in paragraph 19 of Plaintiffs' First Amended Complaint.

20. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants state that Celebrex® at all times relevant had appropriate information in its

FDA approved label. Defendants deny for want of knowledge the remaining allegations contained in paragraph 20 of Plaintiffs' First Amended Complaint.

21. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants further state that they complied with all applicable duties imposed by the law. Defendants deny the remaining allegations contained in paragraph 21, including subparts a-g, of Plaintiffs' First Amended Complaint.

22. Defendants deny the allegations contained in paragraph 22 of Plaintiffs' First Amended Complaint.

23. Defendants deny the allegations contained in paragraph 23 of Plaintiffs' First Amended Complaint.

24. Defendants deny the allegations contained in paragraph 24 of Plaintiffs' First Amended Complaint.

25. Defendants deny the allegations contained in paragraph 25 of Plaintiffs' First Amended Complaint.

26. Defendants admit that the amount sought in Plaintiffs' First Amended Complaint exceeds the jurisdictional limits of the lower courts that would otherwise have jurisdiction over this matter. Defendants deny the remaining allegations contained in paragraph 26 of Plaintiffs' First Amended Complaint.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY DEFECTIVE DESIGN

27. Defendants incorporate each and every admission and denial set forth in paragraphs 1 through 26 above as though fully rewritten herein.

28. Defendants refer to and incorporate their responses in this Answer to paragraphs 2, 4 and 5 of Plaintiffs' First Amended Complaint as though fully rewritten herein. Defendants deny the remaining allegations contained in paragraph 28 of Plaintiffs' First Amended Complaint.

29. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants deny the remaining allegations contained in paragraph 29, including subparts a-e, of Plaintiffs' First Amended Complaint.

30. Defendants refer to and incorporate their responses in this Answer to paragraphs 2, 4 and 5 of Plaintiffs' First Amended Complaint as though fully rewritten herein. Defendants admit that Celebrex® was expected to reach patients without substantial change from the time of sale and further state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants deny the remaining allegations contained in paragraph 30 of Plaintiffs' First Amended Complaint.

31. Defendants deny for want of knowledge the allegations contained in paragraph 31 of Plaintiffs' First Amended Complaint.

32. Defendants deny the allegations contained in paragraph 32 of Plaintiffs' First Amended Complaint.

33. Defendants deny the allegations contained in paragraph 33 of Plaintiffs' First Amended Complaint.

34. Defendants deny the allegations contained in paragraph 34 of Plaintiffs' First Amended Complaint.

35. Defendants admit that the amount sought in Plaintiffs' First Amended Complaint exceeds the jurisdictional limits of the lower courts that would otherwise have jurisdiction over this matter. Further answering, Defendants deny the remaining allegations contained in paragraph 35 of Plaintiffs' First Amended Complaint.

THIRD CAUSE OF ACTION

STRICT LIABILITY FAILURE TO WARN

36. Defendants incorporate each and every admission and denial set forth in paragraphs 1 through 35 above as though fully rewritten herein.

37. Defendants deny for the allegations contained in paragraph 37 of Plaintiffs' First Amended Complaint.

38. Defendants deny for want of knowledge the allegations contained in paragraph 38 of Plaintiffs' First Amended Complaint.

39. Defendants deny for want of knowledge the allegations contained in paragraph 39 of Plaintiffs' First Amended Complaint.

40. Paragraph 40 of Plaintiffs' First Amended Complaint states Plaintiffs' own assertions and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations contained in paragraph 40 of Plaintiffs' First Amended Complaint.

41. Defendants deny the allegations contained in paragraph 41 of Plaintiffs' First Amended Complaint.

42. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Further, paragraph 42 of Plaintiffs' First Amended Complaint states

Plaintiffs' own assertions and legal conclusions to which no response is required. Defendants further state that they complied with all applicable duties imposed by the law. To the extent a response is required, Defendants deny for want of knowledge the remaining allegations contained in paragraph 42 of Plaintiffs' First Amended Complaint.

43. Defendants deny the allegations contained in paragraph 43 of Plaintiffs' First Amended Complaint.

44. Defendants deny the allegations contained in paragraph 44 of Plaintiffs' First Amended Complaint.

45. Defendants deny the allegations contained in paragraph 45 of Plaintiffs' First Amended Complaint.

46. Defendants admit that the amount sought in this case exceeds the jurisdictional limits of lower state courts that would otherwise have jurisdiction over this matter. Further answering, Defendants deny the remaining allegations contained in paragraph 46 of Plaintiffs' First Amended Complaint.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

47. Defendants incorporate each and every admission and denial set forth in paragraphs 1 through 46 above as though fully rewritten herein.

48. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Further Paragraph 48 of Plaintiffs' First Amended Complaint states Plaintiffs' own assertions and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations contained in paragraph 48 of Plaintiffs' First Amended Complaint.

49. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Further Paragraph 49 of Plaintiffs' First Amended Complaint states Plaintiffs' own assertions and legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations contained in paragraph 49 of Plaintiffs' First Amended Complaint.

50. Defendants deny the allegations contained in paragraph 50 of Plaintiffs' First Amended Complaint.

51. Defendants deny the allegations contained in paragraph 51 of Plaintiffs' First Amended Complaint.

52. Defendants deny the allegations contained in paragraph 52 of Plaintiffs' First Amended Complaint.

53. Defendants deny the allegations contained in paragraph 53 of Plaintiffs' First Amended Complaint, and specifically controvert the prayer for relief set forth in that paragraph.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

54. Defendants incorporate each and every admission and denial set forth in paragraph 1 through 53 above as if fully rewritten herein.

55. Paragraph 55 of Plaintiffs' First Amended Complaint states Plaintiffs' own assertions and legal conclusions to which no response is required. Plaintiffs' allegations are also vague and confusing and therefore, to the extent a response is required, Defendants deny for want of knowledge the remaining allegations contained in paragraph 55 of Plaintiffs' First Amended Complaint.

56. Paragraph 56 of Plaintiffs' First Amended Complaint states Plaintiffs' own assertions and legal conclusions to which no response is required. To the extent a response is

required, Defendants deny for want of knowledge the remaining allegations contained in paragraph 56 of Plaintiffs' First Amended Complaint.

57. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants further state that they complied with all applicable duties imposed by the law. Defendants deny the remaining allegations contained in paragraph 57 of Plaintiffs' First Amended Complaint.

58. Paragraph 58 of Plaintiffs' First Amended Complaint states Plaintiffs' own assertions and legal conclusions to which no response is required. To the extent a response is required, Defendants deny for want of knowledge the remaining allegations contained in paragraph 58 contained in Plaintiffs' First Amended Complaint.

59. Defendants deny the allegations contained in paragraph 59 of Plaintiffs' First Amended Complaint.

60. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants further state that they complied with all applicable duties imposed by the law. Defendants deny the remaining allegations contained in paragraph 60, including subparts a-c, of Plaintiffs' First Amended Complaint.

61. Defendants deny the allegations contained in paragraph 61 of Plaintiffs' First Amended Complaint.

62. Defendants deny the allegations contained in paragraph 62 of Plaintiffs' First Amended Complaint.

63. Defendants deny the allegations contained in paragraph 63 of Plaintiffs' First Amended Complaint.

64. Defendants deny the allegations contained in paragraph 64 of Plaintiffs' First Amended Complaint.

65. Defendants admit that the amount sought in this case exceeds the jurisdictional limits of lower state courts that would otherwise have jurisdiction over this matter. Further answering, Defendants deny the remaining allegations contained in paragraph 65 of Plaintiffs' First Amended Complaint.

SIXTH CAUSE OF ACTION

FRAUD

66. Defendants incorporate each and every admission and denial set forth in paragraph 1 through 65 above as if fully rewritten herein.

67. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants deny the remaining allegations contained in paragraph 67 of Plaintiffs' First Amended Complaint.

68. Defendants deny the allegations contained in paragraph 68 of Plaintiffs' First Amended Complaint.

69. Defendants deny the allegations contained in paragraph 69 of Plaintiffs' First Amended Complaint.

70. Defendants deny the allegations contained in paragraph 70 of Plaintiffs' First Amended Complaint.

71. Defendants deny the allegations contained in paragraph 71 of Plaintiffs' First Amended Complaint.

72. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package insert. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants further state that they complied with all applicable duties imposed by the law. Defendants deny the remaining allegations contained in paragraph 72, including subparts a-e, of Plaintiffs' First Amended Complaint.

73. Defendants deny the allegations contained in paragraph 73 of Plaintiffs' First Amended Complaint.

74. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants deny the allegations contained in paragraph 74 of Plaintiffs' First Amended Complaint.

75. Defendants deny the allegations contained in paragraph 75 of Plaintiffs' First Amended Complaint.

76. Defendants deny the allegations contained in paragraph 76 of Plaintiffs' First Amended Complaint.

77. Defendants deny the allegations contained in paragraph 77 of Plaintiffs' First Amended Complaint.

78. Defendants deny the allegations contained in paragraph 78 of Plaintiffs' First Amended Complaint.

79. Defendants deny the allegations contained in paragraph 79 of Plaintiffs' First Amended Complaint.

80. Defendants admit that the amount sought in this case exceeds the jurisdictional limits of lower state courts that would otherwise have jurisdiction over this matter. Further answering, Defendants deny the remaining allegations contained in paragraph 80 of Plaintiffs' First Amended Complaint.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

81. Defendants incorporate each and every admission and denial set forth in paragraph 1 through 80 above as if fully rewritten herein.

82. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants further deny the remaining allegations contained in paragraph 82 of Plaintiffs' First Amended Complaint.

83. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants further deny the remaining allegations contained in paragraph 83 of Plaintiffs' First Amended Complaint.

84. Defendants deny the allegations contained in paragraph 84 of Plaintiffs' First Amended Complaint.

85. Defendants deny the allegations contained in paragraph 85 of Plaintiffs' First Amended Complaint.

86. Defendants deny the allegations contained in paragraph 86 of Plaintiffs' First Amended Complaint.

87. Defendants state that Celebrex® was designed, manufactured, marketed, advertised, distributed, and sold consistent with applicable law and its FDA approved package

insert. Defendants state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants further state that they complied with all applicable duties imposed by the law. Defendants deny the remaining allegations contained in paragraph 87, including subparts a-e, of Plaintiffs' First Amended Complaint.

88. Defendants deny the allegations contained in paragraph 88 of Plaintiffs' First Amended Complaint.

89. Defendants state that they are without knowledge regarding any actions of Merck (which is not a defendant in this matter) and therefore deny any such allegations for want of knowledge contained in paragraph 89 of Plaintiffs' First Amended Complaint. Defendants further state that Celebrex® at all times relevant had appropriate information in its FDA approved label. Defendants deny the remaining allegations contained in paragraph 89 of Plaintiffs' First Amended Complaint.

90. Defendants deny the allegations contained in paragraph 90 of Plaintiffs' First Amended Complaint.

91. Defendants deny the allegations contained in paragraph 91 of Plaintiffs' First Amended Complaint.

92. Defendants deny the allegations contained in paragraph 92 of Plaintiffs' First Amended Complaint.

93. Defendants deny the allegations contained in paragraph 93 of Plaintiffs' First Amended Complaint.

94. Defendants deny the allegations contained in paragraph 94 of Plaintiffs' First Amended Complaint.

95. Defendants admit that the amount sought in this case exceeds the jurisdictional limits of lower state courts that would otherwise have jurisdiction over this matter. Further answering, Defendants deny the remaining allegations contained in paragraph 95 of Plaintiffs' First Amended Complaint.

EIGHTH CAUSE OF ACTION

WRONGFUL DEATH

96. Defendants incorporate each and every admission and denial set forth in paragraph 1 through 95 above as if fully rewritten herein.

97. Defendants deny the allegations contained in paragraph 97 of Plaintiffs' First Amended Complaint.

98. Defendants deny the allegations contained in paragraph 98 of Plaintiffs' First Amended Complaint.

99. Defendants deny the allegations contained in paragraph 99 of Plaintiffs' First Amended Complaint and specifically controvert the prayer for relief set forth therein.

100. Defendants deny each and every remaining allegation of Plaintiffs' First Amended Complaint not expressly admitted herein and specifically controvert the prayer for relief set forth in the unnumbered paragraph below paragraph 99 of Plaintiffs' First Amended Complaint.

AFFIRMATIVE DEFENSES

1. Plaintiffs' First Amended Complaint fails to state a claim upon which relief can be granted.

2. Plaintiffs' claims are barred or otherwise limited by operation of any applicable statute of limitations and/or statute of repose.

3. Plaintiffs have failed to join a party or parties necessary for the just adjudication of this claim.

4. Plaintiffs and their decedents were contributorily negligent, which contributory negligence constitutes a proximate cause of harm to Plaintiffs.

5. Any injuries or expenses incurred by Plaintiffs and their decedents were not caused by Celebrex®, but were proximately caused, in whole or in part, by an underlying disease, idiosyncratic reaction or operation of nature.

6. Plaintiffs and their decedents alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

7. Any injuries or expenses incurred by Plaintiffs and their decedents were proximately caused by the negligence or fault of one or more other persons or entities over whom Defendants had no control and for whose conduct Defendants are not accountable, and who are not parties to this lawsuit, and any recovery by the Plaintiffs should be diminished accordingly.

8. Plaintiffs' alleged damages were not proximately caused by any act or omission by these Defendants.

9. Defendants affirmatively deny that they violated any duty owed to Plaintiffs or their decedents.

10. Plaintiffs' claims are barred pursuant to the Learned Intermediary Doctrine or the Informed Intermediary Doctrine and/or the principle of the Restatement (Second) of Torts § 388, as a manufacturer has no duty to warn patients or the general public of any risk, contraindication or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the physician and the medical profession, which act as a "learned intermediary" in determining the use of the product.

Celebrex® is a prescription medical product, available only on the order of a licensed physician. At all times relevant Celebrex® had appropriate information in its FDA approved label.

11. Plaintiffs' claims are barred by the doctrine of res judicata and/or collateral estoppel.

12. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. The Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. The Plaintiffs' causes of action against Defendants, therefore, fails to state a claim upon which relief can be granted; such claim, if allowed, would conflict with applicable federal law and violate the Supremacy of Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

13. The warning, labeling, advertising and sale of Celebrex® complied at all times with the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 300 et seq. and the Federal Trade Commission Act, 15 U.S.C. § 41 et seq. Consequently Plaintiffs' First Amended Complaint is preempted by these acts and compliance with these acts constitutes a complete or partial defense to the allegations contained in Plaintiffs' First Amended Complaint, including any claim for punitive damages. Alternatively, Defendants are entitled to a presumption that Celebrex® is and was not defective or unreasonably dangerous and that its labeling is and was adequate.

14. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

15. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

16. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

17. Plaintiffs' claims are barred under § 402A comment k of the Restatement (Second) of Torts and § 4, et seq. of the Restatement (Third) of Torts: Products Liability.

18. Plaintiffs' claims against Defendants are barred under § 6(c) of the Restatement of Torts (Third) Products Liability.

19. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of comment j to § 402A of the Restatement (Second) of Torts.

20. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

21. These Defendants affirmatively aver that Celebrex® was at all times material to the First Amended Complaint reasonably safe and reasonable fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

22. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed with the generally recognized, reasonably available, and reliable state of the knowledge at the time the drug was manufactured, marketed and distributed.

23. Plaintiffs' and their decedents' alleged injuries/damages were not caused by any failure to warn on the part of Defendants.

24. The Plaintiffs' cause of action is barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by the Plaintiffs or their decedents was prepared in accordance with the applicable standard of care.

25. Plaintiffs' causes of action are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of Celebrex® or because Plaintiffs and their decedents knew of the alleged risks of Celebrex®.

26. Plaintiffs' and Plaintiffs' decedents' alleged injuries/damages, if any, and hence, those of all Plaintiffs, were the result of misuse or abnormal use of the product Celebrex®.

27. Defendants affirmatively aver that the product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

28. One or more of Plaintiffs' claims for damages are subject to statutory limits on certain types of damages, and this Court is without jurisdiction to enter judgment for Plaintiffs beyond the limitations set forth in the Ohio Revised Code.

29. Some or all of Plaintiffs' claims are barred by their assumption of the risks associated with their use of Celebrex®, or where applicable, their decedents' assumption of the risk associated with their use of Celebrex®.

30. Plaintiffs' claims for punitive damages, which are denied, are subject to limitations set forth in the Ohio Revised Code Section 2315.21.

31. Ohio Senate Bill 120 and Senate Bill 80, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiffs' claims, including the limits and restrictions on damages set forth therein.

32. Plaintiffs' claims for breach of warranty, express and implied, against Defendants are barred based upon the absence of privity.

33. Plaintiffs' claims for breach of warranty, express and implied, are barred by Plaintiffs' failure to give reasonable notice of such alleged breaches.

34. Plaintiffs' claim for punitive damages is unconstitutional and, in the event punitive damages were to be awarded against Defendants, any such award would violate the United States Constitution, and/or the Constitution of the State of Ohio.

35. Plaintiffs' claim for punitive damages is barred by the proscription of the Eighth Amendment to the United States Constitution, as applied to the states through the Fourteenth Amendment, prohibiting the imposition of excessive fines.

36. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the First Amended Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Ohio. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of state conduct, conduct that complied with

applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs or Plaintiffs' decedents; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs or Plaintiffs' decedents and to the amount of compensatory damages; if any; (5) permits jury consideration of net worth or other financial information relating to this Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent.

37. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

WHEREFORE, having fully answered the First Amended Complaint, Defendants request the First Amended Complaint be dismissed with prejudice at Plaintiffs' costs, and that Defendants may have judgment for their costs and attorneys' fees herein.

Respectfully submitted,

/s/Robert C. Tucker
ROBERT C. TUCKER (0013098)
MATTHEW P. MORIARTY (0028389)
RTucker@tuckerellis.com
MMoriarty@tuckerellis.com
Tucker Ellis & West LLP
1150 Huntington Bldg.
925 Euclid Ave
Cleveland, OH 44115-1475
Telephone: 216.592.5000
Telefax: 216.592.5009

Attorneys for Defendants

JURY DEMAND

Defendants hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

/s/Robert C. Tucker
One of the Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2005, a copy of the forgoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system. A copy was also sent by regular U.S. Mail to the following:

Kenneth J. Ignozzi
DYER, GAROFALO, MANN & SCHULTZ, LPA
131 N. Ludlow Street, Suite 1400
Dayton, Ohio 45402

And

J.P. Sawyer
Navan Ward, Jr.
Andy Birchfield
BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C.
PO Box 4160
Montgomery, Alabama 36103-4160

Attorneys for Plaintiffs

/s/Robert C. Tucker
One of the Attorneys for Defendants